

THE CLAIMS

The following is a complete listing of the pending claims.

1. (Previously presented) A method of making a collection device for cells, comprising the steps of:
 - (a) providing a tube having an open end and a closed end;
 - (b) preloading compounds including:

an anticoagulant agent, and
a fixative agent into said tube, said fixative agent selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethyolol-5,5 dimethylhydantoin, dimethylol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, quaternary adamantine and combinations thereof; wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells, and thereby allowing said cells to be directly analyzed by a flow cytometer without further treatment;
 - (c) placing a closure at said open end of said tube; and
 - (d) drawing an amount of vacuum inside said tube to a predetermined level, wherein said amount of vacuum to be drawn is such that pressure differential between atmospheric pressure outside said tube and pressure within said tube is at least sufficient to allow a predetermined volume of said cells to be collected.
2. (Original) The method of Claim 1, wherein said anticoagulant agent is selected from the group consisting of ethylene diamine tetra acetic acid (EDTA), salts of EDTA, ethylene glycol tetra acetic acid (EGTA), salts of EGTA, hirudin, heparin, citric acid, salts of citric acid, oxalic acid, salts of oxalic acid, and a combination thereof.
3. (Original) The method of Claim 1, wherein concentration of said fixative agent is less than about 1 g/ml.

4. (Original) The method of Claim 1, wherein concentration of said anticoagulant agent is less than about 0.3 g/ml.
5. (Original) The method of Claim 1, wherein said preloading step includes preloading a polyacylic acid into said tube.
6. (Original) The method of Claim 1, wherein ratio of said compounds and a final composition comprising said cells and said compounds is less than about 2:100.
7. (Previously presented) The method of Claim 1, wherein said cells are selected from the group consisting of whole blood, epithelial cells, bone marrow, spinal fluid, abnormal tissue sample in a cellular suspension, and a combination thereof.
8. (Previously presented) The method of Claim 1, further comprising the step of sterilizing said compounds before said compounds are preloaded into said tube.
9. (Previously presented) The method of Claim 1, further comprising the step of sterilizing at least all surface areas of said tube and said closure that can come into physical contact with said collected and preserved cells before said compounds are preloaded into said tube.
10. (Previously presented) The method of Claim 1, further comprising the step of providing at least one component selected from the group consisting of an alcohol swab, a gauze, a tube holder, a tourniquet, a glove, other cell collection tube, a needle, a lancet, adhesive strip, syringe, a test strip, a strip containing reagents for cell analysis, a packaging means for storing said at least one component and said collection device to form a kit, and a packaging means for transporting said collection device.

11. (Previously presented) The method of Claim 1, wherein said preloading step further comprises the step of freeze drying said compounds inside said tube.
12. (Previously presented) The method of Claim 1, further comprising the step of screening said collected and preserved cells using an instrument selected from the group consisting of: a flow cytometer, a hematology analyzer, H3 by Bayer Corporation, the Beckman Coulter STKS System, the Beckman Coulter Gen-S System, the Abbott Cell-Dyn 4000 Hematology System, Bayer ADVIA 120 System, the Sysmex XE2100 System, and other analyzers and a combination thereof.
13. (Previously presented) The method of Claim 12, wherein said step of screening said collected and preserved cells is for a purpose selected from the group consisting of: HIV, HPV, hepatitis, leukemia, cancer, and a combination thereof.
14. (Previously presented) A collection device for cells comprising:
 - (a) a collection container having an open end and a closed end, a closure at said open end of said container, wherein said container has an internal pressure less than atmospheric pressure outside said container; and
 - (b) compounds positioned within said container, wherein said compounds include an anticoagulant agent and a fixative agent selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethyolol-5,5 dimethylhydantoin, dimethylol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1 aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1 aza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1 aza-3,7-dioxabicyclo [3.3.0]octane, quaternary adamantine and combinations thereof, inside said tube, wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells, and thereby allowing said cells to be directly analyzed by a flow cytometer without further treatment.

15. (Original) The device of Claim 14, wherein said anticoagulant agent is selected from the group consisting of ethylene diamine tetra acetic acid (EDTA), salts of EDTA, ethylene glycol tetra acetic acid (EGTA), salts of EGTA, hirudin, heparin, citric acid, salts of citric acid, oxalic acid, salts of oxalic acid, and a combination thereof.
16. (Original) The device of Claim 14, wherein concentration of said fixative agent is less than about 1 g/ml.
17. (Original) The device of Claim 14, wherein concentration of said anticoagulant agent is less than about 0.3 g/ml.
18. (Original) The device of Claim 14, wherein compounds further includes a polyacrylic acid.
19. (Original) The device of Claim 14, wherein ratio of said compounds and a final composition comprising said cells and said compounds is less than about 2:100.
20. (Previously presented) The device of Claim 14, wherein said cells are selected from the group consisting of whole blood, epithelial cells, bone marrow, spinal fluid, abnormal tissue sample in a cellular suspension, and a combination thereof.
21. (Original) The device of Claim 14, wherein said compounds are sterile.
22. (Original) The device of Claim 14, wherein at least all surface areas of said tube and said closure that can come into physical contact with said cells are sterile.
23. (Previously presented) A kit comprising the device of Claim 14 and at least one component selected from the group consisting of an alcohol swab, a gauze, a tube holder, a tourniquet, a glove, other cell collection tube, a needle, a lancet, adhesive strip, syringe, a test strip, a strip containing reagents for cell analysis, a packaging

means for storing said at least one component and said collection device to form a kit, and a packaging means for transporting said collection device.

24. (Previously presented) The device of Claim 14, wherein compounds contained in said tube are freeze dried.
25. (Previously presented) The device of Claim 14, wherein said device is used along with an instrument selected from the group consisting of: a flow cytometer, a hematology analyzer, H3 by Bayer Corporation, the Beckman Coulter STKS System, the Beckman Coulter Gen-S System, the Abbott Cell-Dyn 4000 Hematology System, Bayer ADVIA 120 System, the Sysmex XE2100 System, and a combination thereof to provide screening of said cells.
26. (Previously presented) The device of claim 14, wherein said device is used in screening said cells for a purpose selected from the group consisting of: HIV, HPV, hepatitis, leukemia, cancer, and a combination thereof.
27. (Previously presented) A method for preparing cells for analysis, said method comprising the steps of:
 - (a) providing a closed collection container having an internal pressure less than atmospheric pressure outside said container, wherein said collection container contains compounds including an anticoagulant agent and a fixative agent selected from the group consisting of: diazolidinyl urea, imidazolidinyl urea, dimethoylol-5,5 dimethylhydantoin, dimethyol urea, 2-bromo-2.-nitropropane-1,3-diol, oxazolidines, sodium hydroxymethyl glycinate, 5-hydroxymethoxymethyl-1-1aza-3, 7-dioxabicyclo [3.3.0]octane, 5-hydroxymethyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, 5-hydroxypoly[methyleneoxy]methyl-1-1aza-3,7-dioxabicyclo [3.3.0]octane, quaternary adamantine and combinations thereof inside said tube, wherein said compounds are in a sufficient amount to preserve said cells' original morphology and antigenic sites without significant dilution of said cells; and
 - (b) collecting said cells in said collection container.